UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA, *ex rel.* JULIE LONG, *Plaintiffs,* v. JANSSEN BIOTECH, INC., *Defendant.*	Civil Action No. 16-CV-12182-FDS ORAL ARGUMENT REQUESTED

DEFENDANT'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR JUDGMENT ON THE PLEADINGS

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INTRODUCTION

Defendant Janssen Biotech, Inc. ("Janssen") respectfully submits this memorandum of law in support of its Motion for Judgment on the Pleadings pursuant to the public disclosure bar of the False Claims Act ("FCA") and Federal Rule of Civil Procedure Rule 12(c). The Court recently dismissed as time-barred all of Relator's FCA claims for conduct prior to October 28, 2010. *See* ECF No. 372 (Jan. 27, 2023). Because it is clear that Relator's allegations were publicly disclosed years before she filed this litigation, the Court should similarly dispose of Relator's remaining claims and award judgment on the pleadings to Janssen under Rule 12(c).

Back in 2007, in Courtroom 19 of this very courthouse, Judge Saris conducted a bench trial in the *Average Wholesale Price* ("*AWP*") litigation concerning Janssen's marketing of the infusible arthritis medication Remicade—ultimately ruling that Janssen was not liable under the fraud-related claims advanced by the plaintiffs in that case.[1] As part of the *AWP* trial, multiple Janssen witnesses and numerous exhibits disclosed and directly addressed the core theory pursued by Relator here—that Janssen provided extensive education to physicians to assist them in opening and optimizing in-office infusion ("IOI") suites for Remicade. The trial materials disclosed many of the same programs and initiatives to educate physicians on the practical aspects of IOI that Relator now claims were secret kickbacks. For example, the trial materials disclosed that Janssen provided education to doctors about (a) Remicade billing, coding, and reimbursement; (b) the financial implications of prescribing Remicade; and (c) detailed recommendations for suite

[1] *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, at 14–16 (D. Mass. 2007) ("*AWP*") (attached as Ex. L) (all exhibit pincites refer to ECF pagination). Janssen requests that the Court take judicial notice of the exhibits to the Posner Declaration (filed concurrently), which are either public records or otherwise indisputably authentic. *See, e.g.*, *U.S. ex rel. Winkelman v. CVS Caremark Corp.*, 118 F. Supp. 3d 412, 421 n.6 (D. Mass. 2015) ("[T]he Court 'may take judicial notice of public records or indisputably authentic documents on a 12(b)(6) motion.'" (quoting *Branch v. FDIC*, 825 F. Supp. 384, 398 n.8 (D. Mass. 1993)).

staffing and suite design, like what kind of infusion chairs to use.[2] One Janssen witness, in fact, proudly detailed and defended these educational programs as "tools to physicians to help them not only get over some of those disincentives and obstacles that they had, but also to be able to deliver those infusions in a more effective and efficient manner on an ongoing basis."[3]

The *AWP* litigation is not the only time Janssen's marketing of Remicade to physicians for IOI has been the subject of federal litigation. Years before this case, two old declined *qui tam* complaints also disclosed the same allegations Relator advances in this case about Janssen educating physicians on the practical aspects of establishing and managing an IOI practice. *See U.S. ex rel. Heineman v. Johnson & Johnson*, No. 05-cv-2633 (D.N.J.); *U.S. ex rel. Greer v. Johnson & Johnson d/b/a Centocor*, No. 07-cv-1660 (D. Minn.). The *Greer* complaint detailed Janssen's use of "a Practice Management Program as a mechanism to present profit scenarios to practitioners" administering Remicade through IOI.[4] And like this case, the *Heineman* Complaint took issue with Janssen's alleged use of "reimbursement specialists" who "conducted 'business reviews' for [physician] practice[s]" and "independent consultants that advise providers on how to run a profitable [IOI] practice," as well as Janssen's alleged "assist[ance]" to "physicians in acquiring infusion chairs and establishing infusion suites to allow for their administration of" Remicade.[5]

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[2] *See* Plaintiff's Trial Ex. 252 at 13, *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007), No. 01-cv-12257 (Nov. 14, 2006) (attached as Ex. I).

[3] 30(b)(6) Deposition of John Hoffman at 12, *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007), No. 01-cv-12257, ECF No. 1326-7 (attached as Ex. B).

[4] Complaint, *Greer v. Johnson & Johnson* at ¶ 20, No. 07-cv-1660 (D. Minn. Mar. 26, 2007), ECF No. 1 (attached as Ex. O).

[5] Complaint, *U.S. ex rel. Heineman v. Johnson & Johnson*, 02-cv-40469 (S.D. Iowa Sept. 2, 2002) at ¶¶ 48, 28 (available as Certified Copy of Transfer Order, *U.S. ex rel. Heineman v. Johnson & Johnson*, No. 05-cv-2633 (D.N.J. May 20, 2005), ECF No. 17-17) (attached as Ex. N).

Taken either together or separately, the disclosures in *AWP*, *Heineman*, and *Greer* mandate dismissal under the FCA's public disclosure bar. In *U.S. ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 208–09 (1st Cir. 2016), the First Circuit stated that the "ultimate inquiry" of the public disclosure bar is "whether the government has received fair notice, prior to the suit, about the potential existence of the fraud." Permitting a suit to proceed after such notice, the First Circuit noted, would contravene "the core purpose of the FCA: to encourage suits by individuals with valuable knowledge of fraud unknown to the government." *Id.* at 210.

Winkelman set forth a three-part test for determining whether public disclosures preclude the filing of a later-in-time *qui tam* action. That test is easily met here. First, the prior disclosures must expose the "essential elements" of the alleged fraud. *Id.* at 208. The chart included on pages 19–22, *infra*, demonstrates that not only were the essential elements of Relator's alleged fraud disclosed in *AWP*, *Heineman*, and *Greer*, but many of the particular details she emphasizes in her Second Amended Complaint ("SAC") were, as well. Second, the trial materials in the *AWP* litigation and the *qui tam* complaints in *Heineman* and *Greer* are all qualifying public disclosures, because they were made in "a Federal . . . civil . . . hearing in which the Government or its agent [was] a party." 31 U.S.C. § 3730(e)(4)(A) (2010). Third, and finally, the earlier public disclosures were undoubtedly "substantially similar" to the SAC. *Winkelman*, 827 F.3d at 205–06. In assessing substantial similarity, the First Circuit looks to whether the "anatomy of th[e] scheme" has already been "revealed." *Id.* at 210. As confirmed by the aforementioned chart, the public disclosures included statements by Janssen and allegations by earlier *qui tam* relators that Janssen was providing the exact type of IOI education Relator complains of here in an effort to increase IOI of Remicade—the very "scheme" alleged in the SAC. Finally, Relator cannot avail herself of the "original source" exception to the public disclosure bar, as her allegations add nothing material

to existing prior disclosures. *See* 31 U.S.C. § 3730(e)(4)(B) (2010). For these reasons, the Court should award judgment on the pleadings to Janssen on Relator's remaining claims.

STATEMENT OF THE ISSUE

Relator's core allegation is that Janssen provided "kickbacks . . . in the form of valuable business advisory services that the Company regularly provided free of charge to rheumatology and gastroenterology practices throughout the country to help the practices establish infusion suites (so the practices would directly administer Remicade and Simponi ARIA infusions) and then, once opened, to help the practices operate the infusion businesses more efficiently and profitably (so the practices would grow their infusion businesses by prescribing and infusing more Remicade and/or Simponi ARIA.)" Second Amended Complaint ("SAC") ¶ 5, ECF No. 55 (Feb. 11, 2020); *see also* Memorandum and Order on Defendant's Motion to Dismiss, ECF No. 75, at 1 (Oct. 21, 2020) ("Janssen provided a variety of free business advisory services to rheumatology and gastroenterology practices that prescribed and infused Remicade and Simponi ARIA," including "presentations, advice, and customized analysis on how to run a profitable infusion business," and that, "by providing these services, Janssen violated the Anti-Kickback Statute [AKS], and caused physicians to submit false claims for reimbursement to Medicare and Medicaid in violation of the [FCA]."). Prior to the filing of this suit in late 2016, the marketing of Remicade to physicians for IOI had already been the subject of three prior federal litigations against either Janssen (formerly known as Centocor Ortho Biotech Inc. and Centocor, Inc.) or J&J.[6] Those litigations repeatedly disclosed, in great detail, the alleged conduct here—*i.e.*, Janssen's efforts to encourage IOI by educating physicians on how to establish and operate an IOI practice.

[6] As the Court and Magistrate Judge Kelley are aware, discovery orders in this case have compelled the production of documents that, in some instances, date back decades to the period of these three federal litigations.

I. The *AWP* Trial Publicly Disclosed the Same Efforts by Janssen to Educate Physicians About IOI of Remicade Alleged by Relator Here.

AWP was a multidistrict litigation assigned to Judge Saris in the District of Massachusetts. The Master Consolidated Complaint ("MCC") was filed in September 2002.[7] Between late 2006 and early 2007, following extensive discovery, Judge Saris conducted a three-week bench trial in which J&J and Janssen's predecessor company, Centocor, were among the defendants, ultimately finding them not liable. *AWP* Order, Ex. L, at 16. Relevant here, *AWP* concerned allegations that Centocor was using "fraudulent[]" methods to persuade doctors to infuse Remicade in the office, with a particular focus on "marketing th[e] spread" (*i.e.*, advertising to physicians the profits they would make through IOI based on the difference between (1) their actual costs to purchase Remicade and (2) the reimbursement they would receive from insurers based on Remicade's allegedly inflated "average wholesale price," or "AWP"). *AWP* Order, Ex. L, at ¶¶ 294–97. In the course of that litigation, Centocor's sales and marketing practices relating to drugs infused in physicians' offices were extensively scrutinized, including testimony and numerous public filings disclosing that Centocor was providing recommendations to physicians that "directly addressed the practical aspects of [IOI] services" for Remicade—the same allegations raised here.[8]

During the *AWP* litigation, senior executives at Centocor testified about specific educational services and programs that the company provided to physicians concerning IOI. John Hoffman, a Vice President at Centocor, testified in a deposition that "there were significant complexities associated with not only setting up initially [IOI] in a physician office, but on an ongoing basis making sure that the billing, coding, reimbursement, scheduling, handling of

[7] Master Consolidated Complaint, *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007), No. 01-cv-12257, ECF No. 148 (attached as Ex. A).

[8] The J&J Defendants' Trial Memorandum at 6, *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007), No. 01-cv-12257, ECF No. 3288 (attached as Ex. F).

infusion reactions, all of the things associated with [IOI]" were addressed. Ex. B, at 13–14. As a result, Centocor established a "practice management program," which was designed "to provide education and tools to physicians to help them not only get over some of those disincentives and obstacles that they had, but also to be able to deliver those infusions in a more effective and efficient manner on an ongoing basis." *Id.* at 12. According to Hoffman, these programs included "help[ing] [physicians] analyze the financial implications of doing [IOI]," and "how to do coding, et cetera." *Id.* at 17–18.[9]

Hoffman's testimony was echoed in a trial declaration by Julie McHugh, President of Centocor from July 2004 to June 2006 and the Company Group Chairman for Global Virology in J&J's Pharmaceuticals Group since July 2006.[10] According to McHugh, Centocor was "dealing with physician specialties (gastroenterologists and rheumatologists) that had very limited familiarity with infusing drugs in their offices, or the costs and risks associated with 'buying and billing' for infused drugs." McHugh Tr. Decl., Ex. J, at 10. Therefore, McHugh explained, "[t]o ensure physicians would administer Remicade in their offices," Centocor "arrange[d] education

[9] *See also, e.g.,* Third Amended Master Consolidated Class Action Complaint at ¶ 453, *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007), No. 01-cv-12257, ECF No. 1781 (attached as Ex. D) ("The J&J Group created promotional materials and worksheets to allow them to market the spread between the published AWP and the actual selling price to doctors. For example, a publication accessible through Defendants' web sites entitled 'Office-Based Infusion Guide' demonstrates Defendants' aggressive marketing of this spread, specifically noting that, '[d]epending on reimbursement, office-based infusion may provide a financial impact to a physician's practice.' Moreover, the 'Financial Analysis' section of the guide includes a 'REMICADE (infliximab) Financial Impact Worksheet,' which enables doctors see in actual dollars how much additional revenue the use of Remicade would bring to their practice.").

[10] Trial Declaration of Julie McHugh at 2, *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007), No. 01-cv-12257, ECF No. 3397 (attached as Ex. J).

for the physicians concerning the mechanics of billings and reimbursements, and respond[ed] to physician concerns about the financial risks and disincentives associated with the drug." *Id*.

The documentary evidence introduced at the trial before Judge Saris further disclosed Centocor's role in helping physicians set up and operate IOI suites. Both parties utilized the "Office-Based Infusion Guide" created by Centocor for physician use, which was a precursor to the brochures and presentations relied on by Relator in this litigation. *See* Pl.'s Trial Ex. 252, Ex. I. The Guide "discussed the practical aspects of [IOI] services." Ex. I, at 5; *see also* Trial Tr., Ex. G, at 4[11] (explaining that the Guide was "intended to show the overall logistics of offering infusions," including "many . . . logistical instructions as well as practical considerations").

The Guide also included detailed recommendations on setting up an IOI suite, ranging from listing technical requirements (*e.g.*, include an "IV pole") to offering advice on how to provide a pleasant patient experience (*e.g.*, include a "Reclining chair," "TV/VCR," and "Magazines/reading materials"). Pl.'s Trial Ex. 252, Ex. I, at 11. These recommendations were so granular as to identify precise requirements for a suite's "essential" and "optional" items. *Id*. The Guide's "Patient Comfort" recommendations also included advice for enhancing the patient experience, such as "Companion/family member seating," having a "bathroom readily accessible," "Drinking & eating," and "Entertainment." *Id.* at 15.

The Guide's advice on the practicalities of offering IOI was similarly specific. This included advice on how to schedule patients and utilize staff to maximize the efficiency of IOI. *See id.* at 14 (advising "schedul[ing] evening sessions when the office is otherwise unused," "conduct[ing] multiple concurrent infusions," and "desiginat[ing] 1 or more clinical staff

[11] Transcript of Bench Trial - Day Five, *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007), No. 01-cv-12257 (attached as Ex. G).

member(s) to administer all REMICADE™ infusions in order to build proficiency in this procedure"). The Guide further gave recommendations on how to receive maximum reimbursement from Medicare, including how to "bill" for Remicade infusion. *See, e.g.*, *id.* at 6 ("Submitted claims should include appropriate diagnosis code(s), procedure codes for supervised infusion and an office visit code, if there is an office visit in addition to the infusion procedure.").

Both parties also utilized Centocor's "Marketing Plan" for Remicade.[12] This Marketing Plan discussed Centocor's "Integrated Services Strategy," including its "Admin Supplies Plan," "Reimbursement Support Plan," and "Infusion Services Support." *Id.* at 3. This included educating physicians on the practical aspects of IOI, as "[m]ost [gastroenterologists] are comfortable with infusing [Remicade] in their office, once they understand what is involved." *Id.* at 25. According to the Plan, Centocor would seek to "ensure" that the "[o]ffice staff understands what supplies are needed," as well as "how to access" and "administer" Remicade. *Id.* at 26. These strategies included "[d]eploy[ing] a well-trained field force to educate providers in coding and billing," "[e]stablish[ing] a reimbursement hotline service to aid providers," and assisting with "coding and billing" for Remicade. *Id.* at 23.

The *AWP* plaintiffs also introduced the "Remicade™ Practice Management Assistant."[13] This document was a tool "designed to help [physicians] assess the economic impact of providing [IOI] of REMICADE™," including "estimat[ing] both the costs and income associated with an investment in the overhead and staff needed to administer REMICADE™ in an office setting." *Id.*

[12] Plaintiff's Trial Ex. 249, *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007), No. 01-cv-12257 (Dec. 18, 2006) (attached as Ex. K); *see also* Court's Exhibit List Plaintiff's Exhibits in Evidence at 8, *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 20 (D. Mass. 2007), No. 01-cv-12257, ECF No. 5280-2 (attached as Ex. M).

[13] Plaintiff's Trial Ex. 289, *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007), No. 01-cv-12257 (Nov. 14, 2006) (attached as Ex. H).

at 2. The document further "provide[d] worksheets that assist [physicians] in accounting the cost of setting up your office to perform [IOI]," including "spreadsheets to help [physicians] calculate potential income from providing [IOI] of REMICADE™ based on insurer payment policies and [their] patient mix of various payers," which "allow[ed] [physicians] to evaluate the total costs and potential income of providing [IOI] and calculate an investment time to payback." *Id.*

Many of these testimonial and documentary disclosures were then re-disclosed in J&J's trial briefing. *See, e.g.*, J&J Trial Mem., Ex. F, at 6 (explaining goal of "educat[ing] these physicians and overcom[ing] their natural reluctance to incur the cost of providing infusion services"); *id.* (stating materials "were designed, in part, to enable physicians to determine whether providing in-office Remicade infusions would be financially viable given the individual characteristics of their practices"); J&J Sur-Reply Mem., Ex. C, at 8[14] ("Because in-office administration requires the physician to pay for special infusion equipment, staff time and office space, physicians needed to know whether infusing Remicade made economic sense."); J&J Proposed Findings of Fact, Ex. E, at 7–8[15] ("Centocor engaged physicians in discussions relating to the practical aspects of infusion, including its financial implications . . . because rheumatologists were generally unfamiliar with the practice of purchasing and administering drugs in their offices, and would not have been willing to administer Remicade in their offices if it was not economically viable.").

[14] The Johnson & Johnson Group's Sur-Reply Memorandum in Opposition to Class Certification, *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007), No. 01-cv-12257, ECF No. 1325 (attached as Ex. C).

[15] The J&J Defendants' Proposed Findings of Fact and Conclusions of Law, *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007), No. 01-cv-12257, ECF No. 3289 (attached as Ex. E).

Ultimately, Judge Saris concluded that J&J and Centocor were not liable under the theories advanced by the plaintiffs in that litigation. *AWP* Order, Ex. L, at 14–16. As part of her findings, Judge Saris found that, based on the exhibits and testimony adduced at trial, "Centocor developed and implemented a Practice Management Program ('PMP') to educate physicians on buying, infusing, and billing for Remicade," including having "reimbursement specialist[s] from Centocor . . . go over [a 'Financial Impact Worksheet'] with physicians and discuss the financial ramifications of using Remicade." *Id.* at 12 (quotation marks omitted).

II. Two *Qui Tam* Actions Unsealed in 2010 Constitute Additional Public Disclosures.

On September 16, 2002—mere weeks following the filing of the MCC in *AWP*—a *qui tam* action was filed under seal against J&J, alleging that the marketing of Remicade for IOI led to the submission of false claims to the federal government. On March 26, 2007, another *qui tam* action was filed under seal raising similar allegations. Both complaints were unsealed in 2010, more than six years prior to Relator filing this suit, and echo the public disclosures in *AWP*.

A. *U.S. ex rel. Heineman v. J&J*, No. 2:05-cv-2633 (D.N.J.)

In *Heineman*, a former Centocor employee filed an FCA action under seal in 2002 in the Southern District of Iowa (later transferred to the District of New Jersey). *See Heineman* Compl., Ex. N. The thrust of the *Heineman* Complaint was that Centocor "marketed Remicade" for IOI using "improper conduct which caused false claims to be made upon the United States Government." *Id.* ¶ 13.

In addition to claims that Centocor "improperly marketed 'the spread'" to physicians, *id.* ¶ 27, the *Heineman* Complaint alleged that Centocor instructed physicians on how to establish and manage a profitable IOI practice. *Id.* ¶ 25(b). For instance, it alleged that "reimbursement specialists" at Centocor "conducted 'business reviews' for the practice[s]" offering IOI. *Id.* These

"business reviews" were allegedly used to "demonstrate to providers what profit they were making off of [Remicade] and how to increase profits by increasing patients." *Id.*

The *Heineman* Complaint also took issue with Centocor's alleged use of "independent consultants that advise providers on how to run a profitable [IOI] practice." *Id.* ¶ 48; *see also id.* ¶ 61(e) (Centocor "[i]mproperly . . . utiliz[ed] consultants as a marketing opportunity to induce increased use of Remicade."). According to the Complaint, "[t]he initial up front cost to a provider to purchase the chairs necessary to administer Remicade and the cost of establishing an area in which patients can comfortably receive the Remicade [IOI], could be an inhibiting factor." *Id.* ¶ 30. Through "preceptorships" set up with these consultants, Centocor "assist[ed] physicians in acquiring infusion chairs and establishing infusion suites to allow for their administration of" Remicade. *Id.* ¶ 28. Centocor thus allegedly "encouraged and allowed its sales force . . . to funnel funds into providers' practices to assist the provider in creating an area in which Remicade could be administered," which "would contain infusion chairs as well as reading material and could even have a television." *Id.* ¶¶ 29, 31.

After the United States declined to intervene, the *Heineman* Complaint was unsealed on May 18, 2010. Unsealing Order, *U.S. ex rel. Heineman v. Johnson & Johnson*, No. 05-cv-02633, at 2–3 (D.N.J. May 18, 2010), ECF No. 31. After failing to show cause as to "why this action should not be terminated for failure to prosecute," Order to Show Cause, *U.S. ex rel. Heineman v. Johnson & Johnson*, No. 05-cv-02633, at 1 (D.N.J. Jan. 11, 2012), ECF No. 32, the suit was dismissed on January 19, 2012. Notice of Dismissal, *U.S. ex rel. Heineman v. Johnson & Johnson*, No. 05-cv-02633 (D.N.J. Jan. 19, 2012), ECF No. 34.

B. *U.S. ex rel. Greer v. J&J d/b/a Centocor*, No. 07-cv-1660 (D. Minn.)

In *Greer*, two former Centocor employees—one of whom, like Relator here, was alleged to be employed as an "Area Business Specialist" during his time at Centocor—filed an FCA action in March 2007 under seal in the United States District Court for the District of Minnesota. *Greer* Compl., Ex. O, at ¶¶ 13, 16.

Among other things, the *Greer* Complaint alleged that Centocor was educating physicians on how to run a profitable IOI business. For instance:

- "Centocor utilized a Practice Management Program as a mechanism to present profit scenarios to practitioners." *Id.* ¶ 20.
- "Centocor employed the use of Medicare Fee Managers who were responsible to provide training and guidance to practitioners for entitlement from Medicare based upon geographic adjustment rates." *Id.* ¶ 21.
- "Centocor utilized its International Rheumatology Network management programs to educate physician members as to the profitability of optimizing the coding for Remicade in order to maximize practice profitability." *Id.* ¶ 23.

The *Greer* Complaint echoed the *Heineman* Complaint's allegations that the "practice of using 'preceptorships' . . . was to encourage the use of Centocor drugs," including Remicade. *Id.* ¶ 31.

After the United States declined to intervene, the *Greer* Complaint was unsealed in May 21, 2010. Order, *U.S. ex rel. Greer v. Johnson & Johnson*, 07-cv-01660, at 1–2 (D. Minn. May 21, 2010), ECF No. 28. The suit was then dismissed without prejudice for lack of prosecution on September 26, 2011. Order for Dismissal Without Prejudice, *U.S. ex rel. Greer v. Johnson & Johnson*, 07-cv-01660 (D. Minn. Sept. 21, 2011), ECF No. 32.

III. Relator Filed This Suit Against Janssen in 2016, Rehashing the Public Disclosures in *AWP*, *Heineman*, and *Greer*.

On October 28, 2016, nearly a decade after the trial in *AWP* and six years after the unsealing of the *Heineman* and *Greer* Complaints, Relator, a Janssen employee from 2003 to 2016, filed her initial Complaint under seal. ECF No. 1. After the United States declined to intervene on August

9, 2019, ECF No. 40, this Court unsealed the then-operative First Amendment Complaint, ECF No. 46. On February 11, 2020, Relator filed the operative SAC. ECF No. 55. Relator's allegations in all three complaints concern Janssen's efforts to market Remicade—and, later, Simponi ARIA—to physicians for IOI, and map closely on to the public disclosures in *AWP*, *Heineman*, and *Greer*.

Because Remicade was the first infusible medicine to treat rheumatic and gastrointestinal diseases, physicians had "concerns regarding the complexities, risks, and time commitments associated with starting a new infusion business." SAC ¶ 121. The SAC targets Janssen's efforts to "allay" physician concerns about IOI. *Id.* According to Relator, "[f]rom at least 2003 through 2016, Janssen engaged in [an] illegal kickback scheme . . . to expand the IOI market and grow sales of Remicade and Simponi ARIA within the IOI market." *Id.* ¶ 118. These "kickbacks were in the form of valuable business advisory services that [Janssen] regularly provided free of charge to rheumatology and gastroenterology practices throughout the country." *Id.* ¶ 5.

The SAC alleges kickbacks in two broad categories:

- *First*, "help[ing] the practices establish infusion suites (so the practices would directly administer Remicade and Simponi ARIA infusions)." *Id.* ¶ 5 (emphasis added). For example, Janssen employees allegedly provided physicians advice and services relating to:
    - *Assessing IOI profitability*. *See, e.g.*, *id.* ¶ 120 ("One of Janssen's principal, longtime strategies for expanding the [IOI] market and growing sales of Remicade and Simponi ARIA was to advise rheumatology and gastroenterology practices about how these drugs offer a lucrative business opportunity."); *id.* ¶ 166(a) ("Janssen analyzed the practice's and each physician's prescribing patterns and showed how the practice could increase profitability by using . . . Remicade or Simponi ARIA.").
    - *Designing IOI suites*. *See, e.g.*, *id.* ¶ 139 (Janssen "assisted the physician practices with designing and setting-up the infusion suites."); *id.* ¶ 140(b) (Janssen assisted with "design and décor selection" and "suite set-up," including "advice and/or assistance regarding . . . making the IOI [suite] more aesthetically pleasing to patients.").
    - *Acquiring IOI equipment.* *See, e.g.*, *id.* ¶ 140(b) (Janssen advised physicians on "selecting and acquiring furniture, equipment and supplies."); *id.* ¶ 141 (describing an

"Efficiency Checklist" setting forth the "various operational and practice management issues about which Janssen advised and educated physician practices," including having "Television/Reading material present for patients").

- *Second,* "help[ing] the practices operate the infusion businesses more efficiently and profitably (so the practices would grow their infusion businesses by prescribing and infusing more Remicade and/or Simponi ARIA)." *Id.* ¶ 5 (emphasis added). For example, Relator alleges that Janssen employees provided advice and services relating to:

  - *Scheduling infusions. See, e.g.*, *id.* ¶ 140(b) ("Janssen provided advice regarding . . . optimiz[ing] scheduling to maximize the infusion suites' profitability."); *id.* ¶ 166(a) ("Janssen advised top accounts on how to maximize their profits by managing their infusion schedules more efficiently so as to perform all infusions in a shorter period of time while minimizing the practices' overhead costs.").

  - *Practice management. See, e.g.*, *id.* ¶ 164 (Janssen "regularly provided these accounts with business operations and practice management advice and services to further grow the infusion businesses and address specific operational issues within the practices' infusion businesses or even their non-infusion businesses."); *id.* ¶ 166(c) ("The objective of the Proactive Practice Management presentation was to help practices manage their operational issues more proactively.").

  - *Maximizing reimbursement. See, e.g.*, *id.* ¶ 166(c) ("The physicians received customized, expert business advice and/or assistance regarding . . . strategies that ensured maximum reimbursement from government and commercial payers while avoiding audits."); *id.* ¶ 166(f) (Janssen gave "formal presentations" to physicians concerning "Billing and Coding for Infusions.").

According to Relator, these services violated the AKS, by "negat[ing] the need for many physicians to hire and pay for outside consultants to assist them in operating their infusion businesses." *Id.* ¶ 138. As a result, Relator alleges, Janssen "caused the health care providers" who received these services "to present claims for reimbursement" of Remicade and Simponi ARIA "that were false or fraudulent" within the meaning of the FCA. *Id.* ¶ 213.[16]

[16] Counts III to XXIX of the SAC allege that Janssen's marketing of IOI also violated certain state-law analogues to the FCA. However, upon Janssen's motion, this Court dismissed each of Relator's "claims brought under the various state-law analogues to the FCA." Memorandum and Order on Defendant's Motion to Dismiss at 35, ECF No. 75 (Oct. 21, 2020).

LEGAL STANDARD

"After the pleading are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." Fed. R. Civ. P. 12(c).[17] Motions based on the FCA's public disclosure bar may be made after the initial pleadings. *See, e.g., U.S. ex rel. O'Keeffe v. Sverdup Corp.*, 131 F. Supp. 2d 87, 96–99 (D. Mass. 2001) (granting summary judgment on six of relator's seven claims pursuant to the public disclosure bar). The "applicable standard of review" for a Rule 12(c) motion for judgment on the pleadings "is identical to the standard of review for motions to dismiss for failure to state a claim under Rule 12(b)(6)." *Jardín De Las Catalinas Ltd. P'ship v. Joyner*, 766 F.3d 127, 132 (1st Cir. 2014). Judgment on the pleadings is thus "proper if—after accepting all well-pleaded facts as true and viewing them in the light most favorable to [the plaintiff] —the complaint fails to allege a plausible right to relief." *Villeneuve v. Avon Prods., Inc.*, 919 F.3d 40, 49 (1st Cir. 2019). In deciding a public disclosure bar motion under Rule 12, the Court "may consider matters of public record and facts susceptible to judicial notice." *Winkelman*, 827 F.3d at 207–08; *see also R.G. Financial Corp. v. Vergara-Nunez*, 446 F.3d 178, 182 (1st Cir. 2006).

The FCA's public disclosure bar requires dismissal "if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed . . . in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party," unless "the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A).[18]

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[17] Janssen's Answer included an affirmative defense pursuant to the public disclosure bar. ECF No. 83, at 54 ¶ 26 (Nov. 18, 2020).

[18] This memorandum discusses only the standards governing the public disclosure bar following its amendment in July 2010. Although the SAC discusses Janssen's alleged conduct beginning in 2003, Relator has stipulated that a six-year statute of limitations applies to her claims, *see*

As the First Circuit explained in *Winkelman*, the "ultimate inquiry" of the public disclosure bar is "whether the government has received fair notice, prior to the suit, about the potential existence of the fraud." *Id.* at 208–09; *see also U.S. ex rel. Bartz v. Ortho-McNeil Pharm., Inc.*, 856 F. Supp. 2d 253, 265–66 (D. Mass. 2012) (finding public disclosure where "th[e] assemblage of publicly disclosed material had set the government squarely on any trail of fraud long before [relator] arrived on the scene with his claims and allegations").

Under *Winkelman*, courts use a three-step test to determine whether the public disclosure bar applies. 827 F.3d at 208. First, a court "examine[s] whether the allegations or transactions identified in the relators' complaint have already been publicly disclosed," such that "the essential elements exposing the particular transaction as fraudulent" have found "their way into the public domain." *Id*. If so, the court proceeds to the second step: "examin[ing] whether that disclosure occurred through one of the statutorily prescribed methods." *Id.* If those "two queries yield affirmative answers," the court moves on to the third step: "examin[ing] whether the allegations or transactions on which the relators' suit rests are substantially the same as the publicly disclosed allegations or transactions." *Id.* "Substantial similarity" exists if the "anatomy of th[e] scheme" has already been "revealed" before the new *qui tam* is filed. *Winkelman*, 827 F.3d at 210.

Once a public disclosure has been shown, the burden shifts to the relator to show that she is an "original source" of her allegations. *See U.S. ex rel. Winkelman v. CVS Caremark Corp*., 118 F. Supp. 3d at 423–24, *aff'd*, 827 F.3d 201 (1st Cir. 2016) ("Plaintiff-relators bear the burden of proving that they are original sources"). To be "an original source," a relator must (1) have "voluntarily disclosed to the Government the information on which allegations or transactions in

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Stipulation, ECF No. 313, and the Court has dismissed all of Relator's FCA claims prior to October 28, 2010, ECF No. 372 (Jan. 27, 2023).

a claim are based" prior to the public disclosures; or (2) "ha[ve] knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions," and "voluntarily provided the information to the Government before filing." 31 U.S.C. § 3730(e)(4)(B). The test is "whether the relator's allegedly new information is sufficiently significant or essential so as to fall into the narrow category of information that materially adds to what has already been revealed through public disclosures." *Winkelman*, 827 F.3d at 211. It is insufficient to "merely add detail or color to previously disclosed elements of an alleged scheme." *Id*. at 213.

ARGUMENT

Relator's allegations are precluded by the public disclosure bar. First, those allegations were publicly disclosed in *AWP*, *Heineman*, and *Greer*, each of which revealed that Janssen was providing education to physicians on how to set up and run an IOI practice. As just one of many other similar examples, both parties to the *AWP* litigation introduced as an exhibit the Office-Based Infusion that Janssen offered to physicians, which "show[ed] the overall logistics of offering infusions," including "many . . . logistical instructions as well as practical considerations." Trial Tr., Ex. G, at 4. Second, the public disclosures here were made through a statutorily prescribed method: federal litigation to which the government (or its agent) was a party. Third, the disclosures in *AWP*, *Heineman*, and *Greer* are substantially similar to the allegations in this case. Relator does nothing but re-allege in greater detail the already-disclosed fact that Janssen educated physicians on how to establish and operate a profitable IOI practice.[19]

[19] As Janssen has previously described in its Motion for Dismissal With Prejudice or Judgment on Claims Prior to October, 28, 2010 (ECF No. 316), the Department of Justice ("DOJ") began an investigation at least as of 2003 concerning Centocor's marketing practices concerning Remicade (and another J&J drug, Retavase), including the issues raised in *AWP* and *Heineman*, with the Government ultimately declining to intervene.

Finally, Relator cannot avail herself of the "original source" exception to the public disclosure bar, because her allegations add nothing material to the disclosures in *AWP*, *Heineman*, and *Greer*. Allowing Relator's suit to proceed would be contrary to the text and purpose of the FCA's *qui tam* provisions. The Court should award judgment on the pleadings to Janssen.

I. The Public Disclosure Bar Requires Dismissal of Relator's Allegations.

A. *Winkelman* Step One: The "Essential Elements" of Relator's Allegations Were Disclosed Many Years Before This Litigation.

In applying the public disclosure bar, courts first "examine whether the allegations or transactions identified in the relators' complaint have already been publicly disclosed." *Id.* at 208. In making that determination, the question is whether "the essential elements exposing the particular transaction as fraudulent find their way into the public domain." *Id.* This first step is easily satisfied by the disclosures in *AWP*, *Heineman*, and *Greer*.

The essential elements of Relator's claim are that Janssen provided "kickbacks . . . in the form of valuable business advisory services that the Company regularly provided free of charge to rheumatology and gastroenterology practices throughout the country to [1] help the practices establish infusion suites (so the practices would directly administer Remicade and Simponi ARIA infusions) and then, once opened, to [2] help the practices operate the infusion businesses more efficiently and profitably (so the practices would grow their infusion businesses by prescribing and infusing more Remicade and/or Simponi ARIA)." SAC ¶ 5; *see also id.* ¶ 121 (similar).[20] That

[20] Relator has continued to describe the crux of her allegations in this way throughout this litigation. *See, e.g.*, Plaintiff's Memorandum of Law in Support of Motion to Require Compliance with the Court's Orders and to Compel Discovery at 4, ECF No. 346 (Dec. 15, 2022) ("From approximately 2003 to mid-2020, Janssen regularly provided . . . a wide variety of practice management and infusion suite operational support and consulting services and related programs . . . to select rheumatology and gastroenterology physician practices nationwide. These services were provided free of charge to help the physician practices open, maintain, and grow their in-office infusion suite ("IOI") businesses and, in turn, induce them to prescribe and infuse Janssen's

is, according to Relator, educating physicians on the practical aspects of IOI in order to encourage its use—standing alone—constitutes a kickback rendering claims *per se* false under the FCA.

That Janssen was providing education to physicians about establishing and operating their IOI practices was clearly, and repeatedly, disclosed in *AWP*, *Heineman*, and *Greer*. The chart below matches just a sampling of disclosures in those cases to allegations in the SAC, illustrating that those disclosures not only revealed Relator's two core allegations, but also many of Relator's particular allegations about Janssen educating doctors on assessing IOI profitability, designing IOI suites, acquiring IOI equipment, practice management, and maximizing reimbursement.

***1) First Core Allegation*: Janssen "help[ed] the practices establish infusion suites (so the practices would directly administer Remicade and Simponi ARIA infusions)." SAC ¶ 5.**

ASSESSING IOI PROFITABILITY	
Second Amended Complaint	***AWP*, *Heineman*, and *Greer***
• "One of Janssen's principal, longtime strategies for expanding the in-office infusion market and growing sales of Remicade and Simponi ARIA was to advise rheumatology and gastroenterology practices about how these drugs offer a lucrative business opportunity." ¶ 120. • "Janssen analyzed the practice's and each physician's prescribing patterns and showed how the practice could increase profitability by using infusible biologics—namely Remicade or Simponi ARIA." ¶ 166(a).	• "Centocor developed materials . . . designed, in part, to enable physicians to determine whether providing in-office Remicade infusions would be financially viable given the individual characteristics of their practices." *AWP*, J&J Trial Mem., Ex. F, at 5–6. • Centocor's "Office-Based Infusion Guide" offered a "Financial Impact Worksheet" to "help [physicians] estimate projected monthly revenues" from in-office infusion. *AWP*, Pl.'s Ex. 252, Ex. I, at 9. • Centocor's "Remicade™ Practice Management Assistant" allowed physicians to "calculate potential income from performing [IOI] of REMICADE™ based on insurer payment policies and [their] patient mix of various payers," and "evaluate the total costs," as well as "calculate an investment time to payback." *AWP*, Pl.'s Ex. 289, Ex. H, at 2–3. • "[R]eimbursement specialists . . . would conduct 'business reviews' for the practice," including "demonstrat[ing] to providers what profit they were

drugs Remicade and Simponi ARIA. Relator alleges that by providing this valuable remuneration to induce doctors to prescribe and administer Remicade and Simponi ARIA infusions to patients, many of whom were insured by Medicare, Janssen violated the [AKS] and the [FCA].").

	making off [Remicade] and how to increase profits by increasing patients." *Heineman* Compl., Ex. N, at ¶ 25(b). • "Centocor . . . present[ed] profit scenarios to practitioners" about Remicade. *Greer* Compl., Ex. O, at ¶ 20.
DESIGNING IOI SUITES	
Second Amended Complaint	***AWP*, *Heineman*, and *Greer***
• Janssen "assisted the physician practices with designing and setting-up the infusion suites." ¶ 139. • Janssen assisted with "design and décor selection" and "suite set-up," including "advice and/or assistance regarding . . . making the IOI [suite] more aesthetically pleasing to patients." ¶ 140(b).	• Centocor's "Office-Based Infusion Guide" explained "Space Requirements" for IOI, noting that "[i]nfusions may be performed in a typical exam room that can accommodate the following equipment," and also provided advice on maximizing "Patient Comfort" and including "Companion/family member seating," "Drinking & eating," and "Entertainment." *AWP*, Pl.'s Ex. 252, Ex. I, at 11, 16.
ACQUIRING IOI EQUIPMENT	
Second Amended Complaint	***AWP*, *Heineman*, and *Greer***
• Janssen advised physicians on "selecting and acquiring furniture, equipment and supplies." ¶ 140(b). • Describing "Efficiency Checklist" for physicians offering IOI, including having "Television/Reading material present for patients." ¶ 141.	• Centocor "assist[ed] physicians in acquiring infusion chairs and establishing infusion suites to allow for their administration of the drug." *Heineman* Compl., Ex. N, at ¶ 28. • Centocor's "Office-Based Infusion Guide" provided lists of "Infusion Suite Equipment," including "Essential Equipment" and "Optional Equipment"; "Administration Supplies"; and "Magazines/reading material" and a "TV/VCR." *AWP*, Pl.'s Ex. 252, Ex. I, at 11–16.

(2) *Second Core Allegation*: Janssen "help[ed] the practices operate the infusion businesses more efficiently and profitably." SAC ¶ 5.

SCHEDULING INFUSIONS	
Second Amended Complaint	***AWP*, *Heineman*, and *Greer***
• "Janssen provided advice regarding . . . optimiz[ing] scheduling to maximize the infusion suites' profitability." ¶ 140(b).	• Centocor's "Office-Based Infusion Guide" instructs: "[d]esignated 'REMICADE™ Clinic' days may be scheduled by offices that are interested in conducting its REMICADE™ infusions on a dedicated day in order to maximize efficiency"; "[a] practice may choose to schedule evening sessions

• Janssen "advise[d] top accounts on how to maximize their profits by managing their infusion schedules more efficiently so as to perform all infusions in a shorter period of time while minimizing the practices' overhead costs." ¶ 166(a)	when the office is otherwise unused"; "[a] practice may choose to designate 1 or more clinical staff member(s) to administer all REMICADE™ infusions in order to build proficiency in this procedure." *AWP*, Pl.'s Ex. 252, Ex. I, at 15. • "[T]here were significant complexities" with "making sure that . . . all of the things associated with" IOI were addressed, including "scheduling," so Centocor "established . . . programs to provide education and tools to physicians to . . . be able to deliver those infusions in a more effective and efficient manner." *AWP*, Hoffman Dep., Ex. B, at 11–12.
PRACTICE MANAGEMENT	
Second Amended Complaint	***AWP*, *Heineman*, and *Greer***
• Janssen "regularly provided . . . business operations and practice management advice and services to further grow the infusion businesses and address specific operational issues within the practices' infusion businesses or even their non-infusion businesses." ¶ 164. • "The objective of the Proactive Practice Management presentation was to help practices manage their operational issues more proactively." ¶ 166(c).	• "Centocor developed and implemented a Practice Management Program ('PMP') to educate physicians on buying, infusing, and billing for Remicade." *AWP*, 491 F. Supp. at 12, Ex. L. • Centocor established a "practice management program," which was designed "to provide education and tools to physicians to help them not only get over some of those disincentives and obstacles that they had, but also to be able to deliver those infusions in a more effective and efficient manner on an ongoing basis." *AWP*, Hoffman Dep., Ex. B, at 11–12. • Centocor's Office-Based Infusion Guide was "intended to show the overall logistics of offering infusions," including "logistical instructions as well as practical considerations." *AWP*, Trial Tr., Ex. G, at 4.
MAXIMIZING REIMBURSEMENT	
Second Amended Complaint	***AWP*, *Heineman*, and *Greer***
• "The physicians received customized, expert business advice and/or assistance regarding . . . strategies that ensured maximum reimbursement from government and commercial payers while avoiding audits." ¶ 166(c).	• "Centocor utilized . . . management programs to educate physician members as to the profitability of optimizing the coding for Remicade in order to maximize practice profitability." *Greer* Compl., Ex. O, at ¶ 23. • Centocor's Marketing Plan included "[d]eploy[ing] a well trained field force to educate providers in coding and billing" and "[e]stablish[ing] a reimbursement hotline service to aid providers in

• Janssen gave "formal presentations" to physicians concerning "Billing and Coding for Infusions." ¶ 166(f).	prior authorizations[,] coding and billing[,] and appealing denied claims." *AWP*, Pl.'s Ex. 249, Ex. K, at 24. • Centocor "help[ed] physicians" on "how to do coding, et cetera" for in-office infusion. *AWP*, Hoffman Dep., Ex. B, at 17–18.

In light of these (and other) disclosures in *AWP*, *Heineman*, and *Greer*, the "essential elements" of Relator's theory of fraud were thus clearly, and repeatedly, publicly disclosed within the meaning of the first step of the *Winkelman* test.

B. *Winkelman* Step Two: The Public Disclosures in *AWP*, *Heineman*, and *Greer* Were Made Through Statutorily Prescribed Methods.

For the public disclosure bar to apply, the disclosures in question must have "occurred through one of the statutorily prescribed methods." *Winkelman*, 827 F.3d at 208. Because the disclosures in *AWP*, *Heineman*, and *Greer* were all made in "a Federal . . . civil . . . hearing in which the Government or its agent [was] a party," 31 U.S.C. § 3730(e)(4)(A), they were made through a statutorily prescribed method. *See U.S. ex rel. Poteet v. Bahler Med., Inc.,* 619 F.3d 104, 113 (1st Cir. 2010) ("[A]s used in the [FCA], 'hearing' is synonymous with 'proceeding.'").

As an initial matter, either the government or an agent thereof is *always* a party to *qui tam* litigation under the FCA. *See, e.g.*, *U.S. ex rel. Holloway v. Heartland Hospice, Inc.*, 960 F.3d 836, 845 (6th Cir. 2022) ("[B]ecause the government is the real party in interest, the relator is the assignee of the Government's damages claim, and the government exerts a fair amount of control over *qui tam* litigation . . . the *qui tam* relator is, in all cases, the government's agent under § 3730(e)(4)(A)(i)."") (quotation marks and citations omitted)); *U.S. ex rel. Vitale v. MiMedx Grp., Inc.*, 381 F. Supp. 3d 647, 656–57 (D.S.C. 2019) (similar); *U.S. ex rel. Gilbert v. Va. Coll. LLC*, 305 F. Supp. 3d 1315, 1321–25 (N.D. Ala. 2018) (similar).

Because both *Heineman* and *Greer* were *qui tam* suits brought under the FCA in federal court, *see supra* 10, those suits thus qualify as federal civil hearings in which an agent of the government was a party. Likewise, the *AWP* multi-district litigation included multiple *qui tam* actions, and for that reason also qualifies as a federal civil hearing to which the government or its agent was a party. *U.S. ex rel. Ven-a-Care of the Fla. Keys, Inc., v. Abbott Laby's, Inc., and Hospira, Inc*., 1:06-cv-11337 (D. Mass.) (*qui tam* suit in *AWP* litigation); *U.S. ex rel. Linnette Sun and Greg Hamilton v. Baxter Healthcare Corp.*, No. 1:08-cv-11200 (D. Mass.) (same).

Disclosures made in the *AWP* litigation also qualify under the FCA for the additional reason that the United States was an interested party and active participant in that litigation. Indeed, other federal courts have treated filings in *AWP* as examples of "disclosures made in qualifying sources." *United States v. CSL Behring, LLC*, 158 F. Supp. 3d 782, 787–89 (E.D. Mo. 2016), *aff'd* 855 F.3d 935 (8th Cir. 2017). For good reason. The United States was listed on the *AWP* docket as an "Interested Party," *see* Docket Report, *AWP*, 01-cv-12257, and in that capacity received notice of all case filings in the multi-district litigation—and made multiple filings itself. *See, e.g.*, Brief of the United States as Amicus Curiae at 1, *AWP*, 892 F. Supp. 2d 341 (D. Mass. 2006) (No. 01-CV-12257), ECF No. 3104 ("THIS DOCUMENT RELATES TO ALL CLASS ACTIONS" in the *AWP* litigation); Supplemental Brief of United States on the Federal Upper Limit, *AWP*, 892 F. Supp. 2d 341 (D. Mass. 2009) (No. 01-CV-12257), ECF No. 6693.

Because *AWP*, *Heineman*, and *Greer* each constitutes a civil hearing in which the Government or its agent was a party, all public filings in those cases were made through a statutorily prescribed method for purposes of the public disclosure bar. As this Court has explained, "any information disclosed through civil litigation and electronically filed on the docket or otherwise publicly available in the clerk's office should be considered a public disclosure for

purposes of section 3730(e)(4)(A)." *In re Pharm. Indus. Average Wholesale Price Litig.*, 538 F. Supp. 2d 367, 377 (D. Mass. 2008); *see also U.S. ex rel. Est. of Cunningham v. Millennium Lab'ys of Cal., Inc.*, 713 F.3d 662, 670 (1st Cir. 2013) (holding that a "prior public disclosure may occur through *any* public document available on the docket in a civil hearing" (emphasis added) (citing *Poteet*, 619 F.3d at 111 (1st Cir. 2010)). The second step of the *Winkelman* analysis is thus also satisfied here.

C. *Winkelman* Step Three: The Public Disclosures in *AWP*, *Heineman*, and *Greer* Are Substantially Similar to Relator's Allegations Here.

Once a defendant has shown that public disclosures were made through a statutorily prescribed method, courts then compare "the substance of the prior disclosures with the substance of the relator's complaint" to determine if the allegations or transactions are "substantially similar." *Poteet*, 619 F.3d at 114. Where "the anatomy of th[e] scheme" has already been "revealed," a new "complaint that targets [the] scheme . . . is barred even if it offers greater detail about the underlying conduct." *Winkelman*, 827 F.3d at 210; *see also, e.g.*, *Dingle v. Bioport Corp.*, 388 F.3d 209, 214–15 (6th Cir. 2004) ("So long as the government is put on notice to the potential presence of fraud, even if the fraud is slightly different than the one alleged in the complaint, the *qui tam* action is not needed."). Consistent with *Winkelman*, as this Court has explained, "[c]ourts considering whether a prior public disclosure of fraud is 'substantially' similar to a specific FCA claim look to whether the disclosure *could* give rise to an inference of a false or fraudulent claim on the government." *U.S. ex rel. Hagerty v. Cyberonics, Inc.*, 95 F. Supp. 3d 240, 258 (D. Mass. 2015), *aff'd sub nom. Hagerty ex rel. United States v. Cyberonics, Inc.*, 844 F.3d 26 (1st Cir. 2016) (emphasis added); *see also Bartz*, 856 F. Supp. 2d at 265–66 (substantial similarity exists if "th[e] assemblage of publicly disclosed material . . . set[s] the government squarely on any trail of fraud" before the *qui tam* is filed); *United States v. CSL Behring, L.L.C.*,

855 F.3d 935, 944 (8th Cir. 2017) (public disclosures "'set the government squarely on the trail," if 'public disclosures contained in different sources' as a whole . . . collectively 'provide information that leads to a conclusion of fraud'" (first quoting *U.S. ex rel. Kester v. Novartis Pharm. Corp.*, No. 11 Civ. 8196, 2015 WL 109934, at *8 (S.D.N.Y. Jan. 6, 2015), then quoting *U.S. ex rel. Gilligan v. Medtronic, Inc.*, 403 F.3d 386, 390 (6th Cir. 2005)).

This third step is easily satisfied because the "anatomy" of the alleged "scheme"—*i.e.*, providing education on how to establish and operate an IOI practice—was disclosed at trial and in many court filings long before Relator filed this suit. *See supra* 19–22 (matching allegations in SAC to corresponding public disclosures in *AWP*, *Heineman*, and *Greer*).

Relator cannot escape the substantial similarity of her allegations of so-called "business advisory services" concerning the establishment and optimization of physicians' IOI suites to the disclosures in *AWP*, *Heineman*, and *Greer* merely by offering additional details about the alleged scheme. *See, e.g. Poteet*, 619 F.3d at 114–15 (rejecting a "slightly more detailed version of a prior allegation" that describes "how" the defendants executed "the same fraudulent scheme"); *see also, e.g.*, *U.S. ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805, 814–15 (11th Cir. 2015) (applying public disclosure bar where relator alleged a scheme of "clinics provid[ing] a wealth of free services," because relator's allegations "significant[ly] overlap[ped]" with "public sources [that] fully disclose[d] that the defendant clinics provided such services"). While the SAC may provide additional details about the education Janssen allegedly provided to physicians, *see* SAC ¶¶ 139–188, the fact that those allegations are substantially similar to the disclosures in *AWP*, *Heineman*, and *Greer* is dispositive at this stage of the *Winkelman* analysis.

The First Circuit's decision in *U.S. ex rel. Banigan v. PharMerica, Inc.,* 950 F.3d 134 (1st Cir. 2020), is instructive. In that case, the relators argued that the public disclosure bar did not

apply because they alleged that a previously disclosed pharmaceutical kickback scheme operated for "a longer period of time," implicated a different kind of unlawful "remuneration," applied to additional "drugs," and utilized "different and more aggressive tactics" than had previously been known. *Id.* at 143–44 (quotation marks omitted). The First Circuit disagreed. As the Court explained, "the fraudulent conduct at the heart of the Medicaid scheme" alleged by relators was substantially similar to what had already been disclosed—*i.e.*, "the use of financial incentives . . . to persuade or mislead doctors to prescribe preferred" drugs. *Id.* at 144. Because the new suit "'target[ed]' the same fraudulent scheme that was [already] revealed," it was substantially similar to existing disclosures, notwithstanding the new details. *Id.* (citing *Winkelman*, 827 F.3d at 210); *accord U.S. ex rel. Maur v. Hage-Korban*, 981 F.3d 516, 526 (6th Cir. 2020) (public disclosure bar applied where relator "presented 'substantially the same allegations' concerning a scheme perpetuated by [the defendant]").

The same conclusion follows here. Indeed, the same considerations Relator might theoretically point to in trying to distinguish her allegations from the public disclosures in *AWP*, *Heineman*, and *Greer* were expressly rejected in *Banigan*—*e.g.*, that Relator's allegations apply to two drugs rather than just one (*i.e.*, Remicade and Simponi ARIA, as opposed to just Remicade) and cover a longer time period than was at issue in *AWP*, *Heineman*, and *Greer* (*i.e.*, because those litigations concluded years ago). *See Banigan*, 950 F.3d at 143; *see also Cause of Action v. Chicago Transit Auth.*, 815 F.3d 267, 282–83 (7th Cir. 2016) (relator's allegations "substantially similar" to public disclosures where the "allegations pertain[ed] to the same entity . . . and describe[d] the same allegedly fraudulent conduct . . . as the publicly disclosed information."); *Poteet*, 619 F.3d at 115 (holding relator's allegations were substantially similar where relator added to public disclosures by specifying a medical device at issue and "describ[ing] in greater

detail how the defendant doctors improperly influenced third-party doctors"); *Winkelman*, 827 F.3d at 210 (explaining relator's allegations were substantially similar to public disclosures because relator's additions only "memorializ[ed] . . . easily inferable deductions" from the publicly disclosed scheme); *Maur*, 981 F.3d at 526 (holding relator's allegations were substantially similar to public disclosures because "[b]oth the public disclosures and [relator's] complaint were levied against the same actor for the same type of fraud").

Finally, if Janssen's efforts to educate physicians about the practical aspects of IOI actually were kickbacks, as Relator alleges, the public disclosures in *AWP*, *Heineman*, and *Greer* did more than merely provide an "inference" that this fraud was occurring. Rather, it was *actually known* that Janssen was engaging in these activities, based on undisputed facts disclosed in open court before Judge Saris in the *AWP* bench trial and described by Janssen in testimony, affidavits, and other court filings. *See, e.g.*, Hoffman Dep., Ex. B, at 13–14 (Centocor established a "practice management program" designed "to provide education and tools to physicians to help them not only get over some of those disincentives and obstacles that they had, but also to be able to deliver those infusions in a more effective and efficient manner on an ongoing basis."); McHugh Decl., Ex. J, at 10 ("To ensure physicians would administer Remicade in their offices," Centocor "arrange[d] education for the physicians concerning the mechanics of billings and reimbursements, and respond[ed] to physician concerns about the financial risks and disincentives associated with the drug."); *AWP* Order, Ex. L, at 13 ("Centocor developed and implemented a Practice Management Program ('PMP') to educate physicians on buying, infusing, and billing for Remicade.").

In short, the disclosures in *AWP*, *Heineman*, and *Greer* satisfy all three steps of *Winkelman*'s test for determining whether a public disclosure has occurred.

II. Relator Is Not an Original Source of Her Allegations.

To qualify as an original source, Relator bears the burden of proving that she "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions," and that she "has voluntarily provided the information to the Government before filing an action under this section." 31 U.S.C. § 3730(e)(4)(B).[21] Although they are separate inquiries, "[t]he question of whether a relator's information 'materially adds' to public disclosures often overlaps with the questions of whether public disclosure has occurred and, if so, whether the relator's allegations are substantially the same as those prior revelations." *Winkelman*, 827 F.3d at 211. At this stage of the analysis, the Court's "task is to ascertain whether the relator's allegedly new information is sufficiently significant or essential so as to fall into the narrow category of information that materially adds to what has already been revealed through public disclosures." *Id*.; *see also Maur*, 981 F.3d at 527 ("[T]he relator must bring something to the table that would add value for the government."). "[T]rumpet[ing] [relator's] personal knowledge" of "specific examples of [the allegedly fraudulent] conduct does not provide any significant new information where the underlying conduct already has been publicly disclosed." *Id*. at 212. Moreover, allegations that merely "add detail about the precise manner in which [a company] operated [a] program, and a relator who merely adds detail or color to previously disclosed elements of an alleged scheme is not materially adding to the public disclosures." *Id*. at 213; *see also U.S. ex rel. Advoc. for Basic Legal Equality, Inc. v. U.S. Bank, N.A.*, 816 F.3d 428, 433 (6th Cir. 2016) ("A

[21] A relator may also qualify as "an original source" by "voluntarily disclos[ing] to the Government the information on which allegations or transactions in a claim are based" *prior* to any public disclosures. 31 U.S.C. § 3730(e)(4)(B). Relator did not do so here. This litigation was filed in October 2016—eight years after the *AWP* decision was handed down in 2008, and more than six years after the *Heineman* and *Greer* Complaints were unsealed in May 2010. There is no indication that Relator disclosed her allegations to the government prior to those disclosures.

qui tam plaintiff 'is not allowed to proceed independently if [it] merely 'adds details' to what is already known in outline" (quoting *U.S. ex rel. Bogina v. Medline Indus., Inc.*, 809 F.3d 365, 370 (7th Cir. 2016) (alteration in original)).

Because the information added by Relator to the voluminous disclosures already in the public record is not material—that is, "sufficiently important to influence the behavior of the recipient" (*i.e.*, the United States)—Relator cannot avail herself of the original source exception. *Winkelman*, 827 F.3d at 211.[22] As discussed, *supra* 19–22, the fact that Janssen was educating physicians on how to establish and operate a profitable IOI business was publicly disclosed repeatedly—and in substantial detail—in *AWP*, *Heineman*, and *Greer*. For instance, in the *AWP* litigation alone, it was disclosed that, "[t]o ensure physicians would administer Remicade in their offices," Centocor "arrange[d] education for the physicians concerning the mechanics of billings and reimbursements," McHugh Decl., Ex. J, at 10; that Centocor had a "practice management program" designed "to provide education and tools to physicians to help them not only get over some of those disincentives and obstacles that they had, but also to be able to deliver those infusions in a more effective and efficient manner on an ongoing basis," Hoffman Dep., Ex. B, at 11; and that Centocor had an Office-Based Infusion Guide to offer comprehensive education to physicians on, *inter alia*, the "essential" and "optional" items for an IOI suite, "schedul[ing]" infusions, and "bill[ing]" for reimbursement. Pl.'s Ex. 252, Ex. I, at 11–15.

[22] Relator also cannot qualify as an original source with respect to conduct post-dating her departure from Janssen in 2016, because she has alleged no basis for having "independent" knowledge about Janssen activities once no longer employed at the company. *See Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 475–76 (2007) (relator not an original source of information relating to former employer's conduct after his termination); *U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 19, 32 (1st Cir. 2009) (relator was an "original source" only for period of employment); *U.S. ex rel. Vuyyuru v. Jadhav*, 555 F.3d 337, 352–53 (4th Cir. 2009) (similar).

While the SAC may "add detail about the precise manner in which" Janssen educated physicians, *Winkelman*, 827 F.3d at 213, those details are immaterial given what had already been disclosed. *See, e.g.*, *Osheroff*, 776 F.3d at 815 (addition of "background information and details relating to the value of the services offered" did not make relator original source even though those details "ma[de] it somewhat more plain that [defendants]' programs could violate" the FCA). While Relator points to specific presentations that Janssen allegedly gave to particular physicians about IOI, "[o]ffering specific examples of . . . conduct does not provide any significant new information where the underlying conduct already has been publicly disclosed." *Winkleman*, 827 F.3d at 212; *see also Maur*, 981 F.3d at 527 (relator not original source despite "cit[ing] nine additional patient examples," where additions offered "nothing significant or new" about "the exact scheme exposed" in public disclosures (quotation marks omitted)). And while Relator alleges that Janssen's conduct lasted beyond the time period at issue in *AWP*, *Heineman*, and *Greer*, "simply asserting a longer duration for the same allegedly fraudulent practice does not materially add to the information already publicly disclosed." *Winkelman*, 827 F.3d at 212; *see also Bogina*, 809 F.3d at 369–70 (relator not original source despite allegations about new defendant receiving "kickbacks," about fraud occurring in additional "facilities," and "that the fraud [was] continuing"). Relator thus cannot carry her burden to show that she is an "original source" under the Act, because none of her allegations are sufficiently important to qualify as "material" within the narrow original source exception to the public disclosure bar.

CONCLUSION

For the foregoing reasons, Janssen respectfully requests that the Court enter judgment on the pleadings to Janssen.

Dated: March 14, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing on this 14th day of March, 2023.

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